UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460



MEMORANDUM

5/4/2018

SUBJECT: Acute Toxicity Review for *MAQUAT 750-M*, EPA Reg. No.: 10324-115

FROM: Narayanan Parthasarathy

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Registrant: Mason Chemical Company

Decision No.: 539556 Submission No.: 1017389 E-Sub No.: 27659

DP No.: 446617 Action Code: 570

MRID No(s).: 47398404, 47398405, 50163103-50163105

| Formulation from label | | | | | |
|------------------------|------------|--|--------|--|--|
| PC code(s) | CAS #(s) | Active Ingredient(s) % w | | | |
| 069105 | 68424-85-1 | Alkyl (50%C ₁₄ , 40%C ₁₂ , 10% C ₁₆) Dimethyl Benzyl | | | |
| | | Ammonium Chloride | | | |
| 069165 | 32426-11-2 | Octyl Decyl Dimethyl Ammonium Chloride | 15.00% | | |
| 069149 | 7173-51-5 | Didecyl Dimethyl Ammonium Chloride | 7.50% | | |
| 069166 | 5538-94-3 | Dioctyl Dimethyl Ammonium Chloride | 7.50% | | |
| | | Other Ingredients | 50.00% | | |
| | | Total 100.00 | | | |

I. BACKGROUND

The Registrant, Mason Chemical Company, has submitted an application to support a label amendment for their product: *MAQUAT 750-M*, EPA Reg. No. 10324-115. The product is formulated for use as Laundry Disinfectant/Sanitizer for Commercial, Industrial, and Non-Medical Institutional use.

II. FINDINGS/RECOMMENDATIONS

The registrant is citing a product, *MAQUAT MQ615M*, EPA Reg. No. 10324-51, to "bridge" the Acute Oral and Acute Dermal Toxicity data. The registrant is also citing the Reregistration Eligibility Decision (RED) for ADBAC and DDAC (US EPA, 2006a and 2006b, respectively) to support the Acute Inhalation Toxicity endpoint. Additionally, the registrant is requesting waivers for Primary Eye Irritation, Primary Skin Irritation, and Skin Sensitization studies based on RED for ADBAC and DDAC.

- **1. Acute Oral Toxicity:** The registrant cites an Acute Oral Toxicity study (MRID 47398404) and claims Acute Oral LD₅₀ is 0.507 g/kg which will place the subject product in Acute Oral Toxicity Category III (MRID 50163103). On the contrary, the Agency previously reviewed the cited study (DP352210; 6/25/2008 & DP438521, 5/25/2017) and the Acute Oral Toxicity endpoint was deemed to be Category II based on mortality.
- **2. Acute Dermal Toxicity:** The registrant cites an Acute Dermal Toxicity study (MRID 47398405) conducted for the cited product *MAQUAT MQ615M* and accepts Category II for this endpoint (MRID 50163103), which concurs with the Agency previous review (DP352210; 6/25/2008 & DP438521; 5/25/2017).

In summary, the subject product is substantially similar to the cited product, *MAQUAT 615-M*, EPA Reg. No. 10324-51, based on CSFs comparison. The acute oral and acute dermal toxicity studies conducted for the cited product are allowed to be "bridged", which place both the Acute Oral and Acute Dermal Toxicity endpoints to be Category II.

- <u>3. Acute Inhalation Toxicity:</u> The subject product contains 50% total quat by weight. The registrant accepts Category II for Acute Inhalation Toxicity endpoint, based on the REDs for ADBAC and DDAC, in lieu of submitting a study for this endpoint (MRID 50163104).
- **4. Primary Eye Irritation and Primary Skin Irritation:** The subject product contains 50% total quat by weight. The registrant requests waivers for Primary Eye Irritation and Primary Skin Irritation endpoints, due to corrosive nature of the product and indicates acceptance of Category I (MRID 50163105). The waiver request is ACCEPTABLE for these endpoints.
- <u>5. Dermal Sensitization</u>: Due to the corrosive nature of the product to skin, the registrant is requesting a waiver for skin sensitization endpoint (MRID 50163105). The waiver request is ACCEPTABLE.

CONCLUSION: The acute toxicity data requirement has been met to support the label amendment of the subject product, *MAQUAT 750-M*, EPA Reg. No. 10324-115.

The acute toxicity profile of MAQUAT 750-M, EPA Reg. No. 10324-115, is currently:

| Study | MRID | Toxicity Category | Status |
|---------------------------|-------------------|----------------------|----------|
| Acute Oral Toxicity | 47398404/50163103 | II | Cited |
| Acute Dermal Toxicity | 47398405/50163103 | П | Cited |
| Acute Inhalation Toxicity | RED/50163104 | П | Assigned |
| Primary Eye Irritation | RED/50163105 | I | Waived |
| Primary Skin Irritation | RED/50163105 | I | Waived |
| Dermal Sensitization | RED/50163105 | Nonsensitizer | Waived |

III. PRODUCT LABELING

- 1. Signal Word: "DANGER", based upon Toxicity categories of the primary eye and skin irritation studies.
- 2. The statement, "KEEP OUT OF REACH OF CHILDREN (KOROC)", is required. It should appear immediately above the front panel signal word **DANGER.**
- 3. The Agency's Label Review Manual (https://www.epa.gov/sites/production/files/2017-09/documents/lrm-complete-aug-2017.pdf) recommends the following human-hazard precautionary statements:

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS:

DANGER: Corrosive. Causes irreversible eye damage and skin burns. May be fatal if swallowed, adsorbed through the skin, or inhaled. Do not get in eyes, on skin or on clothing. Do not breath (vapor or spray mist). Wear a minimum of NIOSH-approved particulate filtering facepiece respirator with any N, R, or P filter; OR a NIOSH-approved elastometric particulate respirator with any N, R, or P filter; OR a NIOSH-approved powdered air purifying respirator with a HE filter. Wear goggles or face shield, rubber gloves and protective clothing when handling. Wash thoroughly with soap and water after handling and before eating, drinking and chewing gum, using tobacco or using the toilet. Remove contaminated clothing and wash before reuse.

IV. FIRST AID STATEMENTS

- **IF IN EYES:** Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing. Call a poison control center or doctor for treatment advice.
- **IF ON SKIN OR CLOTHING:** Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice.
- **IF SWALLOWED:** Call a poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to by a poison control center or doctor. Do not give anything by mouth to an unconscious person.
- **IF INHALED:** Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible. Call a poison control center or doctor for further treatment advice.

NOTE TO PHYSICIAN: Probable mucosal damage may contraindicate the use of gastric lavage.

GENERAL INFORMATION: Have the product container or label with you when calling a poison control center or doctor or going for treatment. For non-emergency and general information on product use, etc., information pertaining to this product, call the National Pesticides Information Center at 1-800-858-7378 (NPIC web site: www.npic.orst.edu). For emergencies, call the poison control center 1-800-222-1222.

This product meets the Agency requirements for Restricted-Use Classification based on data that place it in toxicity category I for primary eye irritation. In lieu of assigning the product Restricted-Use classification, the product manager may consider alternatives such as face shield or goggles (to mitigate the identified hazards). Restricted-Use requirements vary depending upon use sites, e.g., institutional use, residential use, etc. Please refer to the 40 CFR §152.170 for information on Restricted-Use products.

Based upon data placing it in toxicity category I for primary eye irritation, this product meets the Agency requirements for Child-Resistant Packaging (CRP). However, the Agency does not require products that are assigned Restricted-Use status to be placed in CRP in addition to Restricted-Use Classification. CRP requirements vary depending upon use sites, e.g., institutional use, residential use, etc. Please refer to the 40 CFR, §157.22 and 157.24 for CRP requirements and exemptions.

V. REFERENCES

U.S.EPA (2006a): Reregistration Eligibility Decision for Alkyl Dimethyl Benzyl Ammonium Chloride (ADBAC). EPA739-R-06-009, August 2006.

https://archive.epa.gov/pesticides/reregistration/web/pdf/adbac_red.pdf

U.S.EPA (2006b): Reregistration Eligibility Decision for Didecyl Dimethyl Ammonium Chloride (DDAC). EPA739-R-06-008, August 2006.

https://archive.epa.gov/pesticides/reregistration/web/pdf/ddac_red.pdf